

TESTIMONY of  
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Licensure Subcommittee, Michigan Association of Genetic Counselors  
before the  
STATE OF MICHIGAN  
SENATE HEALTH POLICY COMMITTEE

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Chairman Shirkey, Vice Chair Hune and distinguished Members; I am Angela Trepanier, a Certified Genetic Counselor, from Livonia, Michigan. I am an associate professor at Wayne State University where I direct the genetic counseling graduate program and a past president of the National Society of Genetic Counselors. On behalf of Michigan Genetic Counselors we want to thank Senator Emmons for introducing **Senate Bill 331**. I appreciate the opportunity to testify in favor of this important legislation that would provide licensure for certified genetic counselors in Michigan.

**Who are genetic counselors?**

- Genetic counselors are healthcare providers with significant training and expertise in human and medical genetics, patient education, and psychosocial counseling, obtained through a 2-year accredited Masters level program.
- There are 37 accredited graduate programs in the United States including two in Michigan, housed at the University of Michigan and at Wayne State University.
- Genetic counselors are part of a health care team providing information and support to individuals and families concerned about risk of genetic disorders. Genetic counselors: identify individuals and families at risk of genetic conditions and quantify risk, explain inheritance and natural history, identify and review testing options, provide informed consent for genetic testing, discuss management, promote adaptation to genetic risk, and serve as patient advocates.
- Genetic counselors work in a wide range of clinical care, academic, laboratory, research, and biotechnology settings. In Michigan there are currently 124 certified genetic counselors, a majority of whom provide direct patient care in a variety of specialties
- In addition, there are a number of genetic counselors working for the Michigan Department of Health and Human Services on public health genomics programs including newborn screening follow up and chronic disease genomics. *In fact, Michigan is a model state in terms of advancing public health genomics initiatives, especially those related to hereditary breast and ovarian cancer syndrome and sudden cardiac death of the young.*

## **Why do we need genetic counseling licensure?**

SB 331 is extremely important for the following reasons:

**1) It would protect our citizens from the potential harms of receiving inaccurate information about genetic risks that can occur when genetic information is provided by individuals who do not meet minimum education and certification standards.** Documented harms identified in Michigan include misunderstanding or misinterpretation of genetic information (e.g., family history, genetic test result) leading to unnecessary treatment/surgery, lack of necessary screening, treatment or preventative measure, lack of informed consent (state law), financial harms, and avoidable fear or anxiety.

### *Two examples of harm in Michigan*

- A 50 year old female underwent pre-symptomatic genetic testing for Huntington's disease (HD)-an adult onset, progressive neurologic disease-due to a family history of the condition. Genetic testing revealed she would develop the disease; unfortunately the test was interpreted incorrectly and the patient was told she was not at risk. Only when the patient presented with symptoms of the disease 6 years later was the error in test interpretation recognized.
- A 40 year old female presented to her primary care provider looking for testing for a familial BRCA2 mutation carried by both of her sisters. This mutation is associated with a very high lifetime risk for developing breast and ovarian cancer. The provider ordered BCR-ABL testing instead of BRCA2 testing. The patient tested "BCR-ABL" negative and was told she was not at increased risk for cancer. The patient realized how different her report was from her sisters' reports so she self-referred to a genetic counselor. The right test was ordered and the patient tested positive for the BRCA2 mutation. On her first screening breast MRI she was diagnosed with stage II invasive breast cancer. As such, the delay in ordering the right test potentially led to a delay in the identification of this cancer.

**2) It would assure that minimum education, continuing education, and certification standards have been met by individuals using the title of genetic counselor.** This is particularly important given the growing complexity of genetic testing. The number of genomic tests available has increased by 320% over the last 10 years with an estimated 10 new tests coming to market daily

**3) It would provide reassurance that the quality of care in the State of Michigan is comparable to that of neighboring states.** *Nationally, 23 states have enacted licensure legislation including our nearest neighbors: Ohio, Illinois, Indiana, Minnesota, and Pennsylvania.* Without licensure, individuals without appropriate credentials could provide genetic counseling and therefore decrease the quality of services in our state as compared to our neighboring states.

**4) It would ensure that the State of Michigan is working to retain and attract highly educated health care professionals.** As home to two genetic counseling graduate at a time when genetic counselors are in high demand, it is important that we retain as many graduates as possible. Graduates consider the availability of licensure when seeking employment. Without licensure, we may also have a hard time attracting new graduates from outside the state to practice here or may not get the same caliber of graduates as states with licensure get.

- It would likely result in cost savings of healthcare dollars via accurate testing on appropriate individuals. Studies have shown that ealthcare providers without training in genetics often order more expensive genetic testing than is indicated, amounting to unnecessary health care expenditures.
- A number of studies suggest that 30% of genetic tests ordered by providers without specialized training are inappropriate.

**5) It would enable equitable access to genetic counseling services. Without licensure, patients with Michigan Medicaid encounter significant difficulty accessing genetic counselors. Improving access to genetic counselors should reduce costs as more appropriate testing are ordered.**

In conclusion, the Michigan Association of Genetic Counselors is hopeful that the committee will work with Senator Emmons to enact genetic counseling licensure that will ensure the people of Michigan receive quality genetic counselor services. We believe the people of Michigan will be well served. We thank the Chairman and this committee for your attention to this important issue, and we offer ourselves as a resource as you move forward.



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## ***Now is the Time to License Michigan Genetic Counselors***

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### **Genetic Counselor Licensure will provide Michigan citizens:**

- **Protection from harm of receiving inaccurate information about genetic risks from individuals who do not meet minimum education and certification standards.**
  - Numerous cases of physical, psychological, or financial harm due to the inappropriate use or interpretation of genetic information in Michigan have been described.<sup>1,2,3</sup>
  - Errors in care may be inevitable, but regulation through competency guidelines should reduce the frequency.
  - Approximately 30% of non-genetics health care providers misinterpret the results of genetic tests that they order on their patients.<sup>4</sup> These errors in interpretation can have a significant impact on patients and their family members.
- **Cost savings of healthcare dollars via accurate testing on appropriate individuals.**
  - Healthcare providers without training in genetics often order more expensive genetic testing than is indicated, amounting to unnecessary health care expenditures.<sup>5</sup>
- **Assurance that minimum education, continuing education, and certification standards have been met by individuals using the title of genetic counselor.**
  - Genetic counselors hold advanced degrees and are uniquely trained to provide their services.
  - The public and some healthcare providers are generally unaware of the minimal standards for formally trained genetic counselors. In fact, patients report receiving services from what they originally believed to be genetics experts, when in fact the providers of these services had very limited, if any, formal genetics training.
  - The growing availability of direct-to-consumer genetic testing makes the urgency of ensuring the availability and recognition of quality genetic counseling services to patients in Michigan even greater.<sup>6</sup>
  - Human genetics is advancing rapidly, making continuing education critical. In 2017, genetic testing is available for over 5,000 diseases, an increase of over 3,000 diseases over the last 10 years. In the absence of regulation, compliance for important continuing education may be deficient since adherence to professional recommendations is otherwise voluntary and not required to work as a genetic counselor.
- **Reassurance that the quality of care in the state of Michigan is comparable to that of neighboring states.**
  - Some of our nearest neighbors, Ohio, Illinois, Indiana, and Pennsylvania have enacted laws for genetic counseling licensure.
  - Without licensure, individuals without the appropriate credentials could provide genetic counseling and therefore decrease the quality of the service in Michigan as compared to neighboring states with regulation.
- **A mechanism to report, investigate, and sanction claims of incompetent, unethical, and/or unlawful behavior of a genetic counselor.**
  - In the absence of regulation, there are no professional consequences for practicing outside of defined guidelines. Without regulation, incompetent genetic counselors can continue practicing, leaving families in Michigan vulnerable.
- **Guarantee that the state is working to train and retain highly educated health care professionals.**
  - The state of Michigan is home to two graduate training programs in genetic counseling. Graduates of these programs are in high demand and consider the availability of licensure in a state when seeking employment.

#### References:

1. Brierley K et al. Errors in Delivery of Cancer Genetics Services: Implications for Practice. *Conn Medicine*. 2010;74(7):413-425.
2. Brierley K et al. Adverse events in cancer genetic testing: medical, ethical, legal, and financial implications. *Cancer J*. 2012 July-Aug;18 (4):303-9.
3. Bonadies DC et al. Adverse events in cancer genetic testing. The third case series. *Cancer J*. 2014 Jul-Aug;20(4):246-53.
4. Giardiello FM, et al. The use of interpretation of commercial APC gene testing for familial adenomatous polyposis. *NEJM*. 1997;336(12):823-7.
5. Plon SE, et al. Genetic testing and cancer risk management recommendations by physicians for at-risk relatives. *Genet Med*. 2011;13(2):148-54.
6. U.S. Government Accountability Office (GAO). GAO-10-847T. <http://www.gao.gov/products/GAO-10-847T>. Updated July 22, 2010.



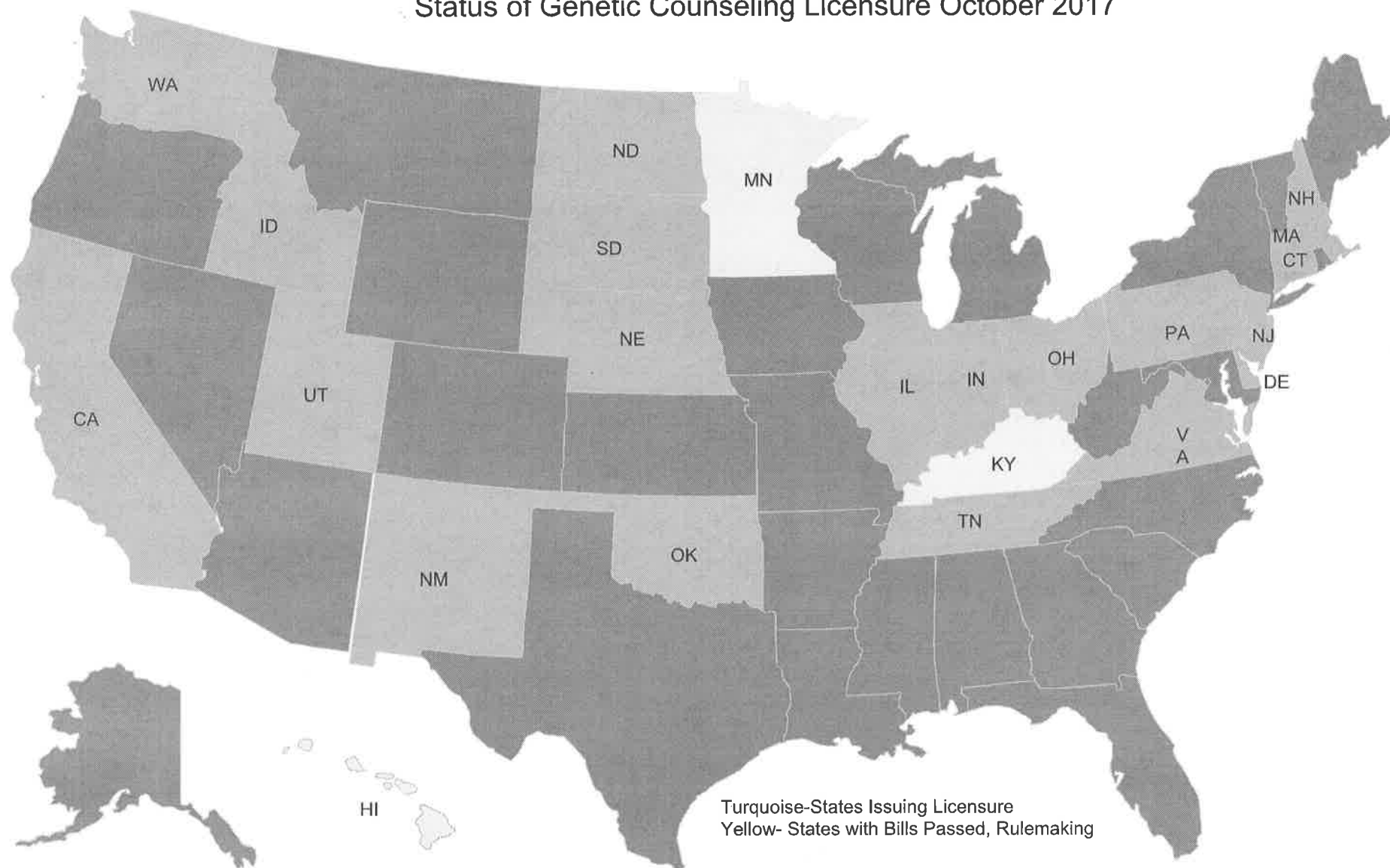
***Genetic counselors are the health professionals specifically trained to address  
the complex issues associated with genetic disease.***

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# Map of the United States

Status of Genetic Counseling Licensure October 2017



## **Genetic Counselors Ensure the Appropriate Utilization of Genetic Services**

Appropriately utilized genetic services can lead to improved clinical outcomes, greater patient satisfaction, and lower healthcare costs. Many studies demonstrate that the lack of involvement by genetic professionals, such as genetic counselors, lead to incorrect and unnecessary genetic testing, test misinterpretation, and an overall inappropriate use of genetic services. This practice leads to unnecessary healthcare costs.

Genetic testing and its implications for appropriate medical care are becoming increasingly complex. Traditional genetic testing that involves identifying a mutation in a single gene is giving way to testing of the entire genome. As a consequence, more patients now rely on the expertise of genetic counselors to guide them through the delivery of these services. *Michigan should enact legislation that provides licensure for genetic counselors. In addition to protecting the public from care from unqualified providers, this will also reduce the misuse of genetic and genomic services and significantly lower costs.*

### **Non-genetics providers are looking for help in delivering genetic services**

According to United Healthcare's recent survey of physicians, 16 percent described themselves as not knowledgeable about genetic science and 75 percent described themselves as only somewhat knowledgeable. As little as 28 percent of physicians felt comfortable interpreting the results of a cancer genetic test. The comfort level was greater among specialists than primary care physicians. Roughly two-thirds of physicians stated that they must reference additional materials to accurately describe the genetic test that they recommend and discuss treatment options with their patients.<sup>1</sup> This suggests that targeted education and referral pathways to genetics professionals would optimize the appropriate utilization of genetic tests and enhance the benefit to the patient.

### **Genetic tests are often incorrectly ordered**

Incorrect genetic testing occurs for many tests and conditions including hematologic disorders, inherited cancer syndromes, neurogenetic conditions, and metabolic conditions, among others, in both the adult and pediatric populations.<sup>2-6</sup> Testing errors often include:

- Ordering tests for the wrong condition or the wrong gene(s).
- Testing with the wrong technology: Ordering full sequence analysis when a mutation had been identified in the family and site specific analysis would have been appropriate.
- Testing the wrong family member: Testing an affected family member increases the chance of identifying the risk factor and provides information for the extended family. Testing an unaffected family member first, who may not have inherited the disease, will often not identify the cause of the disease in the family. A negative result in this unaffected person does not rule

out that specific gene or genes as the cause and it does not provide useful information to other family members.

- Ordering tests in the absence of an indication.

A comparison of tests ordered by non-genetic and genetic providers revealed that up to one-third of tests ordered by non-genetics providers were inappropriate.<sup>2,3</sup>

### **Inappropriate testing costs**

Inappropriate testing costs the public millions of dollars. Due to the extraordinary increase in utilization of tests, some payers are creating pre-authorization criteria. These criteria alone are also inadequate to ensure the appropriate utilization of genetic tests. Data from Michigan based Priority Health in 2009 showed that criteria needed to be accompanied by clinical genetic counseling by a certified genetic counselor who provided a three-generation family history risk assessment. This involvement of a genetic counselor would have prevented the ordering of 25-33 percent of the genetic tests that initially seemed appropriate according to the documentation of the ordering provider.<sup>7-10</sup>

### **Costs associated with misinterpreted tests**

Erroneous genetic risk assessment poses a risk for physical harm and financial harm by quickly incurring additional costs of inappropriate medical procedures. In 2008, the Secretary's Advisory Committee on Genetics, Health, and Society's Executive Summary on the Oversight of Genetic Testing cited numerous cases of healthcare providers with no genetics training incorrectly interpreting family history risks and genetic test results for a variety of health conditions such as Tay Sachs, Cystic Fibrosis, Factor V Leiden, *BRCA1/2*, and FAP.<sup>15</sup>

A landmark paper described how physicians' interpretations of genetic test results were incorrect for almost one-third of patients who underwent genetic tests for familial adenomatous polyposis (a condition associated with a 100-percent risk of colon cancer if not appropriately managed).<sup>16</sup>

Misinterpretation of genetic tests continues to be a concern in the current literature. A documented case example shows family members of a woman with a *BRCA1* mutation who had their ovaries removed due to the high risk for ovarian cancer associated with this gene. Subsequent genetic counseling and genetic testing found that three female family members did not inherit the gene mutation, had no such increased risk, and did not require this costly and invasive intervention. Such deficiencies in genetic knowledge and risk interpretation by non-genetics professionals are not isolated incidences and occur more frequently when genetic specialists are not involved.<sup>1-3,5,6,16,24</sup>



Genetic counseling and genetic testing for patients with hereditary cancer risk results in patients selecting increased cancer surveillance and risk-reducing surgeries that better diagnose early-stage tumors. Genetic counselors also play a role in ensuring the appropriate follow-up, surveillance, and risk reduction for individuals identified to be at increased cancer risk as well as their family.<sup>17</sup> An example is Lynch syndrome, which represents the most-common hereditary cause of colorectal cancer and affects approximately 1 in 400 to 1 in 500 individuals in the general population. Genetic counselors promote cost-effective care of individuals with Lynch syndrome through education regarding appropriate surveillance guidelines and risk-reduction options such as prophylactic surgery. Genetic counselors have expertise in the communication of genetic information among family members, thus further promoting the identification of relatives with inherited cancer risk.<sup>18-21</sup>

## Conclusion

Due to the increased complexity of genetic tests and the implications for appropriate medical care, the healthcare system is increasingly reliant on the expertise of genetic counselors. The rapidly evolving technologies for genetic testing make it difficult for other non-genetic providers to stay abreast of the science. Genetic counselors ensure that patients and healthcare providers make informed decisions regarding the appropriate use of genetic services in medical care and readily ensure appropriate genetic services for the right person, the right test, at the right time. Regulation of this profession supports the goal of providing quality, cost-effective healthcare.

## References:

1. United Healthcare Working Paper 7, March 2012; [www.unitedhealthgroup.com/reform](http://www.unitedhealthgroup.com/reform).
2. Miller C, et al (2011, March) Abstract 377, American College of Medical Genetics Annual Meeting.
3. ARUP Laboratories (2011) *Value of genetic counselors in the laboratory*. Salt Lake City, UT.
4. Sutphen S, et al. *Cancer Res* 2010;70(24 Suppl):Abstract nr P2-10-06.
5. Brierley K, et al. *Conn Medicine*. 2010; 74 (7): 413-425.
6. Brierly KL et al. *Cancer J* 2012;18:303-309.
7. United Healthcare, Dr. Lee Newcomer, Senior Vice President, Oncology -- Fall 2010 *Biotechnology Healthcare* magazine;
8. Aetna, Inc., Dr. Joanne Armstrong, National Medical Director for Women's Health, 2010.
9. Data from Priority Health immediately following the health plan's adoption of medical policies requiring genetic counseling.
10. Informed Medical Decisions, Inc, 2010, data analysis and conclusions; includes consideration of both genetic counseling and testing costs.
11. Venne, V. Invited lecture at a Health Services Research Genomics Meeting, held on Monday, July 16, chaired by Pauline Sieverding, in conjunction with the Veterans Administration Health Sciences Research and Development and Quality Enhancement Research Initiative National Conference 2012, held from July 17 -- 19, unpublished data.
12. Conta JH et.al. abstract "A Strategy to Improve the Quality and Economics of Laboratory Send-outs at Seattle Childrens Hospital: The Role of the Laboratory Genetic Counselor." Presented Abstracts from the Thirty First Annual Education Conference of the National Society of Genetic Counselors (Boston, MA, October 2012). *J Genet Counsel* epub 17August 2012.
13. GenomeWeb Daily News August 15, 2012; [http://www.genomeweb.com/node/1117381?hq\\_e=el&hq\\_m=1324913&hq\\_l=1&hq\\_v=1e6f331b89](http://www.genomeweb.com/node/1117381?hq_e=el&hq_m=1324913&hq_l=1&hq_v=1e6f331b89)
14. Myriad Genetics Laboratory, personal conversation 8/15/12.
15. Secretary's Advisory Committee on Genetics, Health, and Society's Executive Summary on the Oversight of Genetic Testing 2008; [http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS\\_oversight\\_report.pdf](http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_oversight_report.pdf)
16. Giardiello FM et al., *N Engl J Med* 1997;336:823-827.
17. Wham D, et al. abstract "Genetic Counselors Improve Outcomes for BRCA1/2 Positive Patients." Presented Abstracts from the Thirty First Annual Education Conference of the National Society of Genetic Counselors (Boston, MA, October 2012). *J Genet Counsel* epub 17August 2012.

18. Scheuer L, et al. Outcome of preventive surgery and screening for breast and ovarian cancer in BRCA mutation carriers. *Journal of Clinical Oncology* 2002; 20(5):1260-1268
19. Hampel H, Frankel WL, Martin E et al. Feasibility of screening for Lynch syndrome among patients with colorectal cancer. *J Clin Oncology* 2008;26(35):5783-5788.
20. Ladabaum U, Wang G, Terdiman J et al. Strategies to identify the Lynch syndrome among patients with colorectal cancer. *Annals Intern Med* 2011;155(2):69-W30.
21. Mvundura M, Grosse SD, Hampel H, and Palomaki GE. *Genet Medicine* 2010;12(2):93-104.
22. Torrance N, *Br J Cancer* 2006;95:435-444.
23. Griffith GL, *Br J Cancer* 2004;90(9):1967-1703.
24. Klitzman, R et al *J Genet Counsel* 2012; epub 15 May 2012:1-11.